510(K) Summary

AUG 2 4 2011

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K111805

Submitter

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Date Prepared:

June 22, 2011

Name of the device:

- **Trade/Proprietary Name:** ECG Series Electrocardiograph (models ECG-12 Plus, ECG-12, ECG-3F Plus, ECG-3F, ECG-3 Plus, ECG-3)
- **Common Name:** Electrocardiograph
- **Classification:**

Regulation number:	21 CFR 870.2340
Regulation name:	Electrocardiograph

Regulatory Class: Class II
Product Code: DPS

Legally Marketed Predicate Device:

K091513 SE Series Electrocardiograph
K014108 MAC 5000 ECG Analysis System

Device Description:

The ECG Series Electrocardiograph is designed to acquire, analyze, display and record ECG signals from the patient body surface by ECG electrodes. After being amplified, filtered and analyzed, the ECG signal waveforms and analysis results are displayed in the LCD and recorded in the paper through thermal printer or USB printer. ECG data, result and information of patient may be stored in the memory file. The file can be transmitted to a PC through UART or Ethernet interface. Also the device can be configured with the auto analysis software as optional which helps to carry out auto measurement and auto interpretation.

The ECG Series Electrocardiograph device consists of two basic components: the signal acquisition module and central processing unit. Models provide rechargeable battery.

The ECG series electrocardiograph can be divided into two types of devices: the ECG -12, ECG -12 Plus, and the ECG-3F Plus, ECG-3F, ECG-3 Plus and ECG-3 series.

The ECG-3F Plus, ECG-3F, ECG-3 Plus and ECG-3 series are three channel Electrocardiographs, which can print out three channel electrocardiograph waves simultaneously by an 80 mm wide thermal line printer. The different between and ECG-3F and ECG -3 is the shell.

ECG-12 and ECG-12 Plus series are twelve channel Electrocardiographs, and they can print out twelve channel electrocardiograph waves simultaneously by a 216mm wide thermal line printer. The difference between the ECG-12 and ECG-12 Plus is the shell.

Statement of Intended Use:

The intended use of the ECG Series Electrocardiograph is to acquire ECG signals from adult and pediatric patients through the body surface ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and

diagnose heart disease. However, the ECG with measurements and interpretative statements is offered to the clinician on an advisory basis only.

Contraindications
None known at this time

Technological Characteristics:

The technological characteristics of the ECG Series Electrocardiograph have been updated to reflect use of current technology and to incorporate user-requested features. Data in this submission demonstrates that these technological characteristics do not raise new questions of safety or effectiveness.

Test Summary:

Testing was conducted to validate and verify that the ECG Series Electrocardiograph met all design specifications and was substantially equivalent to the predicate devices. The following quality assurance measures were applied to the development of the ECG Series Electrocardiograph:

- Software Testing
- Hardware Testing
- Safety Testing
- Electromagnetic Compatibility Testing

For more information, please see our declaration of conformity to harmonized standards (Exhibit 13).

Conclusion:

Verification and validation testing was done on the ECG Series Electrocardiograph. This premarket notification submission demonstrates that the ECG Series Electrocardiograph is substantially equivalent to the cleared K091513 SE Series Electrocardiograph and K014108 MAC 5000 ECG Analysis System. The device we intent to market has the same intended use and technological characteristics as the K091513 SE Series Electrocardiograph, and therefore does not raise new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Advanced Instrumentations, Inc.
c/o Dr. Jorge Millan
Hialeah Technology Center
601 West 20 St.
Hialeah, FL 33010

AUG 24 2011

Re: K111805
Trade/Device Name: ECG Series Electrocardiograph (models ECG 12 Plus, ECG 12, ECG 3F Plus, ECG 3F, ECG 3 Plus, and ECG 3)
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: August 4, 2011
Received: August 9, 2011

Dear Dr. Millan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K111805

Device Name: ECG Series Electrocardiograph (models ECG-12 Plus, ECG-12, ECG-3F Plus, ECG-3F, ECG-3 Plus, ECG-3)

Indications For Use:

The intended use of the ECG Series Electrocardiograph is to acquire ECG signals from adult and pediatric patients through the body surface ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However, the ECG with measurements and interpretative statements is offered to the clinician on an advisory basis only.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111805